Pharmacy

Step Therapy/Prior Authorization Criteria for Newer Sedative Hypnotics

Background

Zolpidem immediate release (Ambien) is DoD's preferred Uniform Formulary agent in this class and is the sole agent designated Basic Core Formulary. It has a long record of safety and efficacy. Sonata (zaleplon), Ambien CR, Lunesta, Intermezzo, and Silenor are also on the Uniform Formulary, while Rozerem, Edluar and Zolpimist are non-formulary under the Uniform Formulary.

In order to promote use of zolpidem immediate release or Sonata, the step-preferred agents, step therapy/prior authorization requirements apply to Ambien CR, Intermezzo, Lunesta, Silenor, Rozerem, Zolpimist and Edluar. TRICARE coverage of these agents depends on whether you meet step therapy/prior authorization criteria. Zolpimist is not covered.

What is Step Therapy?

Step therapy involves prescribing a safe, cost effective medication as the first step in treating a medical condition. The preferred medication is often a generic mediation that offers the best overall value in terms of safety, effectiveness, and cost. Non-preferred drugs are only prescribed if the generic is ineffective or poorly tolerated.

Ambien CR, Lunesta, Silenor, Rozerem, Intermezzo, Zolpimist and Edluar will only be approved for first time users after they have tried generic zolpidem IR or Sonata.

Prior Authorization Criteria

The following criteria were established by the DoD P&T Committee at their May 2012 meeting. The authorization form for these medications is available at http://pec.ha.osd.mil/forms_criteria.php?

Step Therapy / Prior Authorization Criteria for Ambien CR (zolpidem extended release), Lunesta (eszopiclone), Silenor (doxepin), Rozerem (ramelteon), Intermezzo (zolpidem), Zolpimist (zolpidem spray) or Edluar (zolpidem sublingual)

All current and new users must meet one of the following criteria in order for Prior Authorization to be approved. Automated PA criteria: If the patient has filled a prescription for zolpidem IR or zaleplon at any MHS pharmacy POS (MTFs, retail network pharmacies, or mail order) during the previous 180 days, approval is automatic.

Manual PA criteria:

1. The patient has an inadequate response to, been unable to tolerate due to adverse effects, or has a contraindication to zolpidem IR or zaleplon (e.g., hypersensitivity, aberrant behaviors, or intolerable rebound insomnia).
2. For Edluar, Intermezzo, or Zolpimist the patient is unable to swallow or has swallowing difficulties.
3. For Rozerem, the patient requires a non-controlled agent due to potential for abuse and cannot take Silenor (doxepin).

Criteria approved through the DOD P&T Committee process May 2012

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Newer Sedative Hypnotics Prior Authorization Request Form

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To be completed and signed by the prescriber. To be used only for prescriptions which are to be filled through the Department of Defense (DoD) TRICARE pharmacy program (TPHARM). Express Scripts is the TPHARM contractor for DoD.

PLEASE NOTE:

- **NO prior authorization is required for zolpidem immediate-release tablet (Ambien) or zaleplon (Sonata).**
- Prior authorization for step therapy of the non-preferred agents zolpidem ER (Ambien CR), Edluar, Intermezzo, Lunesta, Rozerem, Silenor, or Zolpimist is NOT required for patients who are currently receiving these medications based on prescriptions filled during the last 6 months, or if there has been a trial of the preferred agent zolpidem immediate-release tablet or zaleplon based on prescriptions filled during the last 6 months.

MAIL ORDER and RETAIL	• The provider may **call**: **1-866-684-4488** or the completed form may be **faxed** to: **1-866-684-4477** • The patient may attach the completed form to the prescription and **mail** it to: **Express Scripts, P.O. Box 52150, Phoenix, AZ 85072-9954** or **email** the form only to: **TpharmPA@express-scripts.com**

Prior authorization criteria and a copy of this form are available at: http://pec.ha.osd.mil/forms_criteria.php

Drug for which Prior Authorization is requested:

- ☐ Ambien CR / zolpidem ER tablet
- ☐ Edluar (zolpidem sublingual tablet)
- ☐ Intermezzo (zolpidem sublingual tablet)
- ☐ Lunesta (eszopiclone)
- ☐ Rozerem (ramelteon)
- ☐ Silenor (doxepin)
- ☐ Zolpimist (zolpidem oral spray)

Step 1 Please complete patient and physician information (please print):

Patient Name: _____ Physician Name: _____

Address: _____ Address: _____

_____ _____

Sponsor ID # _____ Phone #: _____

Date of Birth: Secure Fax #:

Step 2 Please complete the clinical assessment:

1. Has the patient received a trial of zolpidem immediate-release tablet (Ambien) or zaleplon (Sonata) and had an inadequate response?	☐ Yes Please sign and date	☐ No Proceed to Question 2
2. Has the patient received a trial of zolpidem immediate-release tablet (Ambien) or zaleplon (Sonata), but was unable to tolerate it due to adverse effects?	☐ Yes Please sign and date	☐ No Proceed to Question 3
3. Is treatment with zolpidem immediate-release tablet (Ambien) or zaleplon (Sonata) contraindicated for this patient (e.g., due to hypersensitivity, aberrant behaviors, or intolerable rebound insomnia)?	☐ Yes Please sign and date	☐ No Proceed to Question 4
4. Is the medication being prescribed Rozerem or Silenor?	☐ Yes Proceed to Question 5	☐ No Proceed to Question 6
5. Is Rozerem or Silenor considered to be the most clinically suitable choice for this patient due to its apparent lack of abuse potential?	☐ Yes Please sign and date	☐ No Coverage not approved
6. Is the requested medication Edluar, Intermezzo, or Zolpimist AND the patient has swallowing difficulties?	☐ Yes Please sign and date	☐ No Coverage not approved

Step 3 I certify the above is true to the best of my knowledge. Please sign and date:

_____ _____

Prescriber Signature Date

[17 October 2012]